

**NUCLEAR REGULATORY COMMISSION**

**Consolidated Guidance About Materials Licenses:  
Program-Specific Guidance About Medical Use Licenses,  
Issuance and Availability of NUREG**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Notice of availability.

**SUMMARY:** The Nuclear Regulatory Commission (NRC) is announcing the availability of NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses." This document consolidates guidance on medical licensing into a single, comprehensive source and provides guidance for licensing under revised 10 CFR Part 35, "Medical Use of Byproduct Material," which will be effective on October 24, 2002 (67 FR 20249; April 24, 2002; corrections to rule were published in the Federal Register on October 9, 2002; 67 FR 62872). A Summary of Public Comments and NRC Responses will be published as a separate document, Appendix BB to NUREG-1556 Volume 9. These documents will also be available in electronic form on CD-rom.

**ADDRESSES:** A free single copy of final NUREG-1556, Volume 9, and Appendix BB (on paper or CD-rom), may be requested by writing to the U.S. Nuclear Regulatory Commission, ATTN: Mrs. Carrie Brown, Mail Stop T 9-C24, Washington, D.C. 20555-0001; email: CXB@nrc.gov;

telephone: (301) 415-8092. Single copies of the documents, in paper form and on CD-rom, are also available for inspection and/or copying for a fee in the NRC Public Document Room, 11555 Rockville Pike, Rockville, Maryland. NUREG-1556, Volume 9, and Appendix BB will be available on the NRC's website at <<http://www.nrc.gov>> in the electronic reading room and at <http://www.nrc.gov/materials/miau/miau-reg-initiatives/by-product.html>.

**FOR FURTHER INFORMATION CONTACT:** Roger W. Broseus, Rulemaking and Guidance Branch, M/S T 9-C24, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone (301) 415-7608; email [RWB@nrc.gov](mailto:RWB@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

On August 25, 1998 (63 FR 45270), NRC announced the availability of draft NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses," dated August 1998. This draft document, which was prepared by a team composed of NRC staff and staff from State Departments of Health, was published for public comment in parallel with the proposed revision of Part 35, "Medical Use of Byproduct Material." As a result of comments received on the August 1998 draft, it was revised and published as draft NUREG-1556, Volume 9, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Medical Use Licenses" (March 2002). The notice of availability of the March 2002 draft was published on April 5, 2002 (67 FR 16467), and input on the guidance was requested. The NRC invited the public to comment on questions pertaining to the level of detail and format in the guidance, model procedures, licensing guidance specific to diagnostic nuclear medicine, and other guidance that should be considered

for reference in NUREG-1556, Volume 9, such as additional voluntary industry consensus standards or other publically available documents. The March 2002 draft NUREG included Appendix Z, which provided a summary of comments on the 1998 draft and NRC responses.

On April 25, 2002, NRC held a public workshop to obtain stakeholder comments on the March 2002 draft, with emphasis on therapeutic applications of byproduct materials. A second public workshop was held on April 30, 2002, to receive stakeholder input on guidance, with emphasis on diagnostic applications of byproduct materials. In addition to the feedback from the workshops, the NRC also received written public comments during a 60-day comment period (April 5 to June 4, 2002). A summary of comments and NRC responses will be published as a separate Appendix BB to NUREG-1556, Volume 9, which will also include the summary of comments and NRC responses on the August 1998 draft NUREG. The staff considered all comments, including constructive suggestions to improve the document, in the preparation of the final NUREG report.

The final version of NUREG-1556, Volume 9, is now available for use by applicants, licensees, NRC license reviewers, and other NRC staff. This document supersedes the guidance previously found in --

- (1) Regulatory Guide (RG) 10.8, Revision 2, "Guide for the Preparation of Applications for Medical Use Programs";
- (2) Appendix X to RG 10.8, Revision 2, "Guidance on Complying With New Part 20 Requirements";
- (3) Draft RG DG-0009, "Supplement to Regulatory Guide 10.8, Revision 2, Guide for the Preparation of Applications for Medical Use Programs";
- (4) Draft RG FC 414-4, "Guide for the Preparation of Applications for Licenses for Medical Teletherapy Programs";

- (5) RG 8.23, "Radiation Safety Surveys at Medical Institutions, Revision 1";
- (6) RG 8.33, "Quality Management Program";
- (7) RG 8.39, "Release of Patients Administered Radioactive Materials";
- (8) Policy and Guidance Directive (P&GD) 03-02, "Licensing Lixiscope and BMA";
- (9) Policy and Guidance Directive (P&GD) 03-08, "Standard Review Plan for Teletherapy";
- (10) Policy and Guidance Directive (P&GD) 3-17, "Review of Training and Experience Documentation Submitted by Proposed Physician User Applicants";
- (11) Policy and Guidance Directive (P&GD) FC 87-2, "Standard Review Plan for License Applications for the Medical Use of Byproduct Material";
- (12) Policy and Guidance Directive (P&GD) FC 86-4, Revision 1, "Information Required for Licensing Remote Afterloading Devices";
- (13) Addendum to Revision 1 to P&GD FC 86-4, "Information Required for Licensing Remote Afterloading Devices-Increased Source Possession Limits";
- (14) Policy and Guidance Directive (P&GD) FC 92-01 "Information Required for Licensing Mobile Nuclear Medicine Services," and
- (15) Policy and Guidance Directive (P&GD) 3-15, "Standard Review Plan for Review of Quality Management Programs."

Small Business Regulatory Enforcement Fairness Act

In accordance with the Small Business Regulatory Enforcement Act of 1996, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Dated at Rockville, Maryland, this 15<sup>th</sup> day of October, 2002.

For the Nuclear Regulatory Commission.

***/RA/***

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Patricia K. Holahan, Chief  
Rulemaking and Guidance Branch  
Division of Industrial and Medical  
Nuclear Safety, NMSS

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